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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,964	10/12/2000	Geert Maertens	2551-48	5719
23117	7590	11/22/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/686,964	Applicant(s) MAERTENS ET AL.	
	Examiner Myron G. Hill	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36- 41, 44- 49, 62-78, 88-110 is/are pending in the application.
- 4a) Of the above claim(s) 48, 49, 64-75, 79, 89-103, and 105- 107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36- 41, 44- 47, 62, 63, 76-78, 88, 104 and 108- 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 February 2005 has been entered.

Election/Restrictions

Newly submitted claims 64-75, 79, 89-103, and 105- 107 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are drawn to methods of making a product (kit) and have different method steps for each variation of the method. The original claims were drawn to a product, not a method of making a product and the methods would have been subject to restriction because there are many methods to make the same product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64-75, 79, 89-103, and 105- 107 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR

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1.142(b) and MPEP § 821.03. This is a restatement to clarify some dependent claims omitted from the list in the prior action.

Claims 36- 41, 44- 47, 62, 63, 76-78, 88, 104 and 108- 110 are under consideration.

Information Disclosure Statement

A signed and initialed copy of the information disclosure statement filed 6/14/04 is enclosed.

Drawings

The drawings filed 12 October 2000 are accepted for examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 36- 38, 40, 41, and 62- 76, 81 87, 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al. (US 6036579) and Harlow and Lane.

After review, as requested by Applicant, the basis of the rejection is changed to 35 USC 102 without the Harlow and Lane reference.

Rejections Maintained or New

Claim Rejections - 35 USC § 112

Claims 44- 47 and 83- 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to epitopes comprising at least 5-6 amino acid residues selected from the recited group of single amino acids.

Applicant argues that the specification discloses the recited residues on page 17 and these are isolate specific amino acids as well as amended the claims to recite epitopes of 5- 6 residues and that one of skill in the art would recognize that Applicant was in possession of the invention.

Applicant's arguments have been fully considered and not found persuasive.

The claims are not drawn solely to isolated amino acid sequences. The claims are drawn to a solid phase coated with HVC NS3 protein.

The specification has not taught single epitopes that can detect HCV that can be used in the kit.

The prior art recognizes polypeptides to use in an assay kit, see Seidel et al (US 6036579 previously cited) claims 1 and 6-10.

Applicant has not taught specific single linear or conformational epitopes that consist of the recited residues, or what properties (specific sequences that antibodies bind to) these epitopes have over the many other epitopes in the NS3 polypeptide of HCV. Thus, it is concluded that applicant did not have in their possession the full range of epitopes claimed that can function in the kit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36- 38, 40, 41, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Seidel *et al.* (US 6036579).

The claims are drawn to an HCV NS3 immunoassay wherein sulphonation and desulphonation is added in at least one step. The Office considers a “kit” claim to be a product, not a method. That product is what the kit contains/comprises.

It is noted that the claims recite sulphonation and desulphonation as product by process steps. The product claimed now is desulphonated.

Applicant has not pointed out how the product is different than the cited prior art or is different from the previously claimed product. Page 15 of the specification discloses that DTT is used to desulphonate the product.

Seidel *et al.* teach a HCV solid phase coated with NS3 protein that is desulphonated (columns 3, line 59 to column 4, line 4, and Example 3).

Thus, Seidel *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

Claims 36-41, 44- 47, 76, 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel *et al.* (US 6036579) as applied to claims 36- 38, 40, 41, and 76 above, and further in view of Leroux-Roels.

The claims are drawn to an HCV NS3 immunoassay wherein sulphonation and desulphonation is added in at least one step and include SEQ ID# 18 and a choice of sequence variants.

Seidel *et al.* is discussed above. Seidel *et al.* teach that be derived from any arbitrary HCV isolate (column 2, lines 9-12).

Seidel *et al.* do not teach SEQ ID# 18 or variants.

Leroux-Roels teach SEQ ID# 18 as shown in Figure 6 as well as variants of known sequences also shown in Figure 6.

One of ordinary skill in the art at the time of invention would be motivated to use NS3 sequences and be able to select from those known in the art as indicated Seidel *et al.* with the expectation of success because Seidel *et al.* teach that NS3 is useful in

assays and Leroux-Roels provide NS# sequences. One of ordinary skill in the art at the time of invention would have known that fusion proteins are useful in protein expression methods in vitro as taught by Seidel *et al.*

Thus, it would be *prima facie* obvious to use the HCV NS3 sequences of Leroux-Roels with the expectation of success because both are HCV NS3 sequences.

Claims 36-41, 44- 47, 62, 63, 76, 87, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel *et al.* (US 6036579) as applied to claims 36- 38, 40, 41, and 76 above, and further in view of Figard (US 5616460, previously cited).

The claims are drawn to an HCV NS3 immunoassay wherein sulphonation and desulphonation is added in at least one step and include zwitter ionic detergent.

Seidel *et al.* is discussed above.

Seidel *et al.* do not teach zwitter ionic detergent.

Figard teach zwitterionic detergents are surfactants and surfactants are useful to include in buffers for HCV binding because it reduces the non-specific binding of antibodies (column 5 lines 5-35).

One of ordinary skill in the art at the time of invention would be motivated to use zwitterionic detergents with the expectation of success because it is taught to improve assay specificity. Even though the specific detergent is not taught, it would be obvious to use any zwitterionic detergent because members of the same class of compounds are interchangeable.

Thus, it would be *prima facie* obvious to include zwitterionic detergents in the assay buffer with the expectation of success in reducing non-specific binding.

Claims 76-78, 104, and 108- 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al. (US 6036579) as applied to claims 36- 38, 40, 41, and 76 above, and further in view of Icardi *et al.*

Applicant argues that the prior art does not teach the method of sulphonation desulphonation to prepare products as presently claimed, the process of the claims produces a product different than the cited art, and that the rejection is a section 103 and not a section 102.

Applicant's arguments have been fully considered and not found persuasive.

The basis of the rejection is as stated in the previous two rejections.

Applicant has not pointed out how the product is different or how Icardi *et al.* do not make obvious the controls used in the claimed product.

The claims are drawn to a product (with product by process limitations), not a method of making and antigen for an assay. Applicant has not specifically pointed out how the product as claimed is different. Applicant argues that the antigen is "better" but does not show an unexpected result or that the product is different. Applicant argues that the prior art does not teach the method of preparing antigen for the assay as claimed. The claims are not drawn to methods and applicant has not pointed out how the claimed and prior art products are specifically structurally different. The claims require a desulphonated HCV NS3 protein. The prior art teaches such a protein

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preparation for use in a solid phase assay (Seidel *et al.*). The Icardi *et al.* reference is provided to show limitations relating to the solid phase test strip which are not disclosed in Seidel *et al.*

The rejection of record is maintained for reasons above and as cited in the prior action and is also applied to the new claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner



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